REMARKS

The Amendments to the Claims

Applicant has canceled claims 13, 21 and 26, directed to opioids, without prejudice.

In response to the Examiner's comments and to expedite prosecution applicant has amended claims 5 and 6 to delete the recitation of the term "pharmacodynamic equivalent thereof." Applicant has also amended claim 5 to delete the recitation of "opioid," without prejudice.

Applicant has amended claims 20 and 25 to replace the recitation of "opioid" in the claims with the recitation of "cocaine and nicotine". Both of these claims depend from claim 5, wherein the addictive drug is selected from the group consisting of cocaine and nicotine. Support for this amendment may be found, e.g., on page 15, lines 27-29 of the specification, and claim 4 of the application as originally filed.

Claims 1, 11-13, 21 and 26 have been canceled and claims 2-4, 7-10 and 22-24 have been withdrawn. Applicant reserves the right to pursue the subject matter of any canceled or withdrawn claims in future applications claiming benefit herefrom.

None of the amendments to the claims constitutes new matter. Claims 5-6, 14, 15-20 and 25 are now pending in this application.

THE OFFICE ACTION

Applicant acknowledges with appreciation the Examiner's withdrawal of the rejection of claims 5-6 for lack of scope of enablement, and the rejection of claims 5,

13, 20-21 and 25 under 35 U.S.C. § 102(b) as being anticipated by Peyman (WO 9842275, of record) ("Peyman"), in view of Applicant's January 15, 2004 Amendment.

Rejections under 35 U.S.C. §112, First Paragraph

Written Description

The Examiner has rejected claims 5-6, 20-21 and 25-26 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time of filing. The Examiner contends that the claim amendments of January 15, 2004, reciting "a kit...comprising a first receptacle...a second receptacle," constitute new matter. The Examiner states that there is no disclosure in the specification for a kit or a receptacle. Applicant traverses.

The specification describes, at page 19, lines 4-23, a blister pack containing "an amount of formulations...for example tablets or suppositories, which is sufficient, initially, for the first phase, followed by a corresponding amount of tablets containing the combination of agonists of the glucocorticoid and/or mineralocorticoid receptors." Applicant asserts that such blister pack describes a kit. Accordingly, applicant requests that the Examiner withdraw this rejection.

Rejections under 35 U.S.C. §112, Second Paragraph

Indefiniteness

Claims 5-6, 12-13, 20-21, and 25 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has maintained her indefiniteness rejection of the terms "pharmacodynamic equivalent thereof", "a high dose" and "higher amount for the initial dose." The Examiner refers to the reasons of record for the rejection, namely that "pharmacodynamic equivalent" is not clearly defined in the specification and that "high dose" and "higher amount for the initial dosage" are relative terms. Thus, the Examiner asserts that applicant therefore does not ascertain the metes and bounds as the patent protection desired of these claims.

Applicant traverses in part and amends in part.

First, applicant has deleted the term "pharmacodynamic equivalent thereof" from claims 5 and 6 (and therefore, claims dependent therefrom), thereby obviating this aspect of the rejection.

Second, with respect to the terms "high dose" and "higher amount for the initial dosage," applicant respectfully submits that the terms are clearly defined in the instant application. The specification at pages 20-22 clearly teaches the dosage ranges for the addictive drugs and the corticosteroid receptor agonists. For example, the specification teaches some guidelines for dosage of several opiates, listed in terms of both low and high dose ranges in mg/day (see, page 22, lines 15-20). The specification states, at page 22, line 12-13, that corresponding values of, e.g., nicotine, depend on the relevant dosage thresholds of the undesired side effects. To that end, the specification

also teaches that the highest dose possible for an addictive drug is one "where no severe side effects, possibly deleterious to health, of a chronic administration are to be expected" (see page 22, lines 1-3). Given these teachings, applicant requests that the Examiner withdraw this aspect of the rejection.

Rejections under 35 U.S.C. §103

Obviousness: Peyman

The Examiner has rejected claims 5-6, 13, 20-21 and 25-26, under 35 U.S.C. §103(a) as being unpatentable over Peyman. The Examiner contends that Peyman discloses pharmaceutical compositions, preparations and formulations comprising an opioid in combination with a steroid (preferably a glucocorticoid) as an antiinflammatory compound. The Examiner states that while Peyman does not expressly disclose the above ingredients in a first receptacle and an addictive drug in a second receptacle of a kit, it would have been obvious to do so. The Examiner posits that since various forms of the pharmaceutical compositions, preparations or formulations are described in the form of nose drops, gels, emulsions, etc, they would clearly need to be stored in a container or kit. Applicant traverses, in view of the claim amendments.

Applicant has deleted claims 13, 21 and 26, thereby rendering the rejection of those claims moot. Applicant has also amended independent claim 5 and all pending claims depending therefrom, to delete all recitations of opioid. As amended, the claims recite nicotine, cannabinoid, amphetamine, cocaine, Crack, and MDMA (Ecstacy) as the addictive drug. The method of treatment in Peyman comprises the administration of an opioid (singly, or in combination with other pharmacological agents). The

disclosure in Peyman, directed towards a method of treatment with an opioid, does not teach or suggest any other addictive agent as recited in the currently claimed invention. Applicant respectfully requests that the Examiner withdraw the obviousness rejection to claims 5-6, 13, 20-21 and 25-26.

Obviousness: Capasso and Montgomery

The Examiner has rejected claims 5–6, 12–13, 20–21 and 25-26 under 35 U.S.C. § 103(a) as being unpatentable over Capasso et al. (XP-002100182 ("Caspasso I") and XP-002100187 ("Caspasso II") and Montgomery et al. (XP-002100181) ("Montgomery"). The Examiner asserts that Capasso I and Capasso II disclose that a corticosteroid receptor agonist, i.e., dexamethasone, administered either before or after the administration of an opioid, i.e., morphine, is capable of inhibiting opioid dependency. According to the Examiner, Montgomery also discloses that a corticosteroid receptor agonist, i.e., cortisol, administered either before or after the administration of an opioid, i.e., morphine, is useful for the treatment of opioid dependency.

The Examiner acknowledges that that none of Capasso I, Capasso II or Montgomery discloses a kit comprising a single composition of the addictive drug in combination with the corticosteroid receptor agonist. The Examiner also acknowledges that none of Capasso I, Capasso II or Montgomery discloses the use of the corticosteroid receptor prednisolone to treat opioid dependence. However, the Examiner states that it would have been obvious to one of ordinary skill in the art to both employ a kit as

described above and also to use other corticosteroid receptor agonists, such as prednisolone, in the kit. Applicant traverses, in view of the claim amendments.

As stated above, applicant has deleted claims 13, 21 and 26, thereby obviating the rejection of those claims.

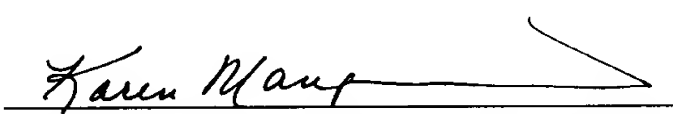
With regard to the pending claims, the teachings of Capasso I, Capasso II and Montgomery all refer to a method for treating *opioid* dependency. As stated above, applicant has amended the claims to remove all recitations of opioids. As amended, the claims recite nicotine, cannabinoid, amphetamine, cocaine, Crack, and MDMA (Ecstacy) as the addictive drug. None of Capasso I, Capasso II and Montgomery, either alone or in combination, teaches or suggests these addictive agents. In view of the claim amendments, applicant asserts that the rejection under 35 U.S.C. § 103(a) in view of Capasso I, Capasso II or Montgomery has been rendered moot and requests that the Examiner withdraw this obviousness rejection.

CONCLUSION

In view of the foregoing claim amendments and remarks, applicant requests that the Examiner favorably reconsider this application and allow the pending claims herein.

If the Examiner believes a telephone conference would expedite allowance of this application, she is invited to telephone the undersigned at any time.

Respectfully submitted,



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